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A Programmatic Approach to EU MDR Compliance

Raland Introduction

Raland Compliance Partners, your trusted partner delivering sustainable, Quality, Regulatory, and Clinical compliance solutions.

Full life-cycle compliance consultation for Medical Device, Pharmaceutical, and Biotech companies worldwide.

- EU MDR Consulting
- Medical Device
- Pharmaceutical and Biotech
- Regulatory Support

EU MDR Timeline

- January 2019 – Notified Body applications
- March 2019 – 13485:2016 Compliance
- March 2020 – EUDAMED live
- May 2020 – New rules for MD products
- May 2021 – UDI Phase-in begins
- May 2022 – New rules for IVD products
- June 2024 – MDD Certificates expire

EC Update 10/17

- January 2019 – Notified Bodies applications
  - ~80 NBs expected to be reduced to ~50
  - Only 33 applications for designation
  - Only 11 onsite audits performed
  - Only 2 NB have submitted CAPA Plans
  - CAPA Plan review and approval is 12 mos.
    - *Unclear when that clock starts*

Who is your NB?

- January 2019 – Notified Bodies in place
  - Have they applied for MDR designation?
  - Have they received an onsite audit?
  - If so, have they submitted CAPA Plans?

- Don’t wait to engage with them

Programmatic Approach

1. Educate
2. Organize
3. Assess
4. Plan
5. Execute
6. Sustain

Programmatic Approach

1. Educate – Your organization
   - Overview
     - Focus changed to product life-cycle approach; safety data
     - Clinical trial data and evaluation
     - Greater oversight of Notified Bodies
     - Reliance on clinical data
     - Review timeline transparency
     - UDI requirements
   - Anticipated EU MDR Compliance Timeline
   - Manufacturer Responsibility
   - Supplier Responsibility
   - Notified Body Responsibility
   - PRRC (Person Responsible for Regulatory Compliance)

Programmatic Approach

1. Educate – Your organization
2. Organize – Your information
   - Compile Existing CE-marked Product List
   - Compile Existing Product Pipeline
   - Compile Existing Supplier List
   - Notified Body Relationship
   - etc.

Programmatic Approach

1. Educate – Your organization
2. Organize – Your information
3. Assess – Your product / processes
   - Product Tech File/Design Dossier
   - Data Governance Process
   - Quality System and Product Lifecycle
   - Supplier Compliance

Programmatic Approach

1. Educate – Your organization
2. Organize – Your information
3. Assess – Your product / processes
4. Plan – Your project
   - Workstreams
   - Timelines
   - Milestones
   - Resource load
   - etc.

Programmatic Approach

1. Educate – Your organization
2. Organize – Your information
3. Assess – Your product / processes
4. Plan – Your project
5. Execute – Your plan
   - Utilize PMO approach to manage workstreams
   - Assign qualified resources
   - Manage and control data
   - Monitor and report progress
   - etc.

Programmatic Approach

1. Educate – Your organization
2. Organize – Your information
3. Assess – Your product / processes
4. Plan – Your project
5. Execute – Your plan
6. Sustain – Compliance
   - Write / revise SOPs
   - Quality System Processes
   - Training program

Keypoints

- Assess your portfolio to determine priority
- Develop a plan that takes into account prioritization of your portfolio
- Execute the plan and ensure that project controls are in place to manage and monitor your progress
- Revise processes and procedures to ensure sustainable processes

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Questions?

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